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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/075,217	02/14/2002	Shai N. Gozani	NEURO-NRO-008	8764

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EXAMINER

APANIUS, MICHAEL

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 05/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/075,217	GOZANI ET AL.	
	Examiner	Art Unit	
	Michael Apanius	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-15, 18-38, 40-42 and 45-62 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 48-54 is/are allowed.
- 6) ☒ Claim(s) 3-15, 18-23, 25-28, 31, 35-38, 40-42, 45-47 and 55-62 is/are rejected.
- 7) ☒ Claim(s) 24, 29, 30 and 32-34 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This office action is in response to the amendment filed 3/1/2006. The Examiner acknowledges the cancellation of claims 1, 2 and 39 and the amendments to claims 48 and 55. Upon further consideration, new rejections are presented below.

Claim Objections

2. Claim 38 is objected to because of the following informalities: it appears that at claim 38, line 3, "response signal" should be --response signal characteristic--.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 14, 15 and 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. At claim 14, "said third anatomical site" lacks proper antecedent basis in the claim. Claim 22 is unclear because "the weighted sum", "the recordings" and "the detectable signal" appear to lack proper antecedent basis. Note that claim 3, lines 8-9, states "each [electrode is] configured to detect a signal". It appears that "the recordings" refers to the detected signal of each electrode, but this is unclear in relation to "the weighted sum" and "the detectable signal".

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 45-47, 56, 59 and 60 are rejected under 35 U.S.C. 102(b) as being anticipated by Lemmen (US 5,327,902). In regards to claim 45, Lemmen discloses an apparatus for assessing physiological function in an individual comprising: a sensor, said sensor comprising: a stimulator (14, 16) and a detector (10, 12) comprising electrodes; wherein said sensor automatically positions said detector substantially adjacent to a second anatomical site when said stimulator is positioned substantially adjacent to a first anatomical site. Although the fixture allows adjustable positioning of electrodes, once the electrode positions are preset, the fixture automatically positions the detector when the stimulator is appropriately positioned. Note that the apparatus is capable of being used when the first anatomical site is the ankle ipsilateral to said second anatomical site. In regards to claims 46 and 47, the apparatus is capable of detecting a compound muscle action potential (CMAP) recorded over a motor point even though the reference may not expressly disclose detecting a CMAP over a motor point. In regards to claims 56 and 60, Lemmon discloses that the apparatus is used in nerve conduction studies to record motor latency (abstract) over a motor point during nerve conduction studies. Note that motor latency is also called distal latency. In

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regards to claim 59, note that the stimulus will also evoke a CMAP and therefore the detected signal will inherently comprise a compound muscle action potential.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 3-15, 18-21, 23, 31, 35-38, 40-42, 45-47 and 59-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Steuer et al. (US 4,711,248) in view of Manoli (US 4,583,549). Steuer discloses an apparatus (see figures 5 and 6) for assessing physiological function in an individual comprising: a sensor, said sensor comprising: a stimulator (113, 114); a detector (115, 116, 117); and flexible wire connectors. In regards to claims 4 and 5, the sensor is shaped to fit a lower extremity and is capable of fitting a foot. In regards to claim 6, the apparatus comprises a processor (figure 3). In regards to claims 7-9, the apparatus measures nerve conduction (last sentence of abstract) and is capable of measuring conduction of the tibial nerve and the peroneal nerve. In regards to claims 10 and 11, the detector has a shape such that it is capable of detecting a signal generated at a superficial location over the extensor digitorum brevis muscle and the abductor hallucis muscle of the foot. In regards to claim 12, the stimulator is capable of being placed over the ankle ipsilateral to the detector placement. In regards to claims 13-15, a positioning indicator (10) is capable of being

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placed over the malleolus of the ankle ipsilateral to the detector placement. In regards to claims 18 and 19, the electrodes of the detector comprise an electrode array of three electrodes of which two are independent interleaved bipolar recording elements. In regards to claims 20 and 21, the detector is inherently capable of detecting a compound muscle action potential over a motor point generated by the electrical stimulation. Note that the location of the detector shown in figures 5 and 6 is considered a motor point. In regards to claim 23, Steuer discloses the method steps in his description of the operation of the apparatus. In regards to claim 31, the detected signal inherently comprises peripheral evoked potentials generated by the electrical stimulation. In regards to claims 35-38, 40-42, 45-47 and 59-62, similar limitations are met as stated above.

9. However, Steuer does not expressly disclose a flexible connector that automatically positions the detector when the stimulator is positioned substantially adjacent to its anatomical site. Manoli teaches a flexible connecting means that automatically positions the other electrodes when one electrode is properly positioned for the purpose of providing an inexpensive, convenient and easy to use connector that ensures proper and automatic positioning of the electrodes (column 2, lines 22-29). Manoli uses a flexible printed circuit board comprising multiple layers of material including a base layer in the form of a sheet of flexible plastic material (MYLAR) and a layer of conductive traces; and an electrical interface (20 in figure 5).

10. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used a flexible circuit board as taught by Manoli to

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automatically position the electrodes of Steuer in order to provide an inexpensive, convenient and easy to use connector that ensures proper and automatic positioning of the stimulating and detecting electrodes.

11. Claims 3, 6-9, 12, 20-23, 26, 31, 35-38, 40, 45-47, 56, and 59-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosier (4,807,643) in view of Manoli (US 4,583,549). Rosier discloses an apparatus for assessing physiological function in an individual comprising: a sensor, said sensor comprising: a stimulator (10) and a detector (24). In regards to claim 6, the apparatus comprises a processor (figure 1). In regards to claims 7-9, the apparatus measures nerve conduction (abstract) and is capable of measuring conduction of the tibial nerve and the peroneal nerve. In regards to claim 12, the stimulator is capable of being placed over the ankle ipsilateral to the detector placement. In regards to claims 20 and 21, the detected signal over a motor point inherently comprises a compound muscle action potential generated by the electrical stimulation. In regards to claim 22, Rosier discloses averaging the results to improve accuracy (column 2, lines 2-4). Note that averaging is a form of a weighted sum. In regards to claim 23, the method steps are carried out during normal operation of the apparatus. In regards to claim 26, distal latency (column 2, line 3) is measured. In regards to claim 31, the detected signal inherently comprises peripheral evoked potentials generated by the electrical stimulation. In regards to claims 35-38, 40, 45-47, 56 and 59-62, similar limitations are met as stated above.

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12. However, Rosier does not expressly disclose a flexible connector that automatically positions the detector when the stimulator is positioned substantially adjacent to its anatomical site. Manoli teaches a flexible connecting means that automatically positions the other electrodes when one electrode is properly positioned for the purpose of providing an inexpensive, convenient and easy to use connector that ensures proper and automatic positioning of the electrodes (column 2, lines 22-29). Manoli uses a flexible printed circuit board comprising multiple layers of material including a base layer in the form of a sheet of flexible plastic material (MYLAR) and a layer of conductive traces; and an electrical interface (20 in figure 5).

13. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used a flexible circuit board as taught by Manoli to automatically position the electrodes of Rosier in order to provide an inexpensive, convenient and easy to use connector that ensures proper and automatic positioning of the stimulating and detecting electrodes.

14. Claims 25, 27, 28, 55, 57 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosier (4,807,643) as modified by Manoli (US 4,583,549) as applied to claims 3, 6-9, 12, 20-23, 26, 31, 35-38, 40, 45-47, 56, and 59-62 above, and further in view of Applicant's admission of prior art. Rosier as modified by Manoli does not expressly disclose measuring F-wave latency, sensory latency and sensory amplitude. However, Applicant discloses at page 13 of the specification that typical nerve conduction measurements include distal motor latency, sensory latency, and sensory

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amplitude. At page 25, line 21 of the specification, Applicant discloses that measurement of F-wave latency is also familiar to those knowledgeable in the art. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have measured F-wave latency, sensory latency and sensory amplitude as admitted prior art by the Applicant in the method of Rosier as modified by Manoli because it is well-known and routine in the art to supplement one measurement with other measurements to help verify and provide further insight into the results of a study.

15. Claims 57 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lemmen (US 5,327,902) in view of Applicant's admission of prior art. Lemmen does not expressly disclose measurement of sensory latency and sensory amplitude. However, Applicant discloses at page 13 of the specification that typical nerve conduction measurements include distal motor latency, sensory latency, and sensory amplitude. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have measured sensory latency and sensory amplitude as admitted prior art by the Applicant in the method of Lemmen because it is well-known and routine in the art to supplement one measurement with other measurements to help verify and provide further insight into the results of a study.

Allowable Subject Matter

16. Claims 48-54 are allowed.

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17. Claims 24, 29, 30, 32-34 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.


Conclusion

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Apanius whose telephone number is (571) 272-5537. The examiner can normally be reached on Mon-Fri 8:30am-5pm.

19. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

20. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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